

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Klautky, et al.
Appl. No. : **10/676,568**
Filed : September 30, 2003
Title : AUTOMATED CYTOLOGICAL SAMPLE CLASSIFICATION
Examiner : Lyle Alexander
Group Art Unit : 1797
Confirm. No. : 7905

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/NancyRushton/
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RESPONSE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This letter is in response to the Office Action dated September 11, 2009. Claims 1, 5-7, 10, 11, 14, 15, 21-24, 28, 29, and 39-41 have not been amended and remain pending in this application. Based on the following remarks, reconsideration and allowance of this application is respectfully requested.

Claim Rejections – 35 U.S.C. §112

Claim 41 stands rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. In particular, the Examiner alleges that claim 41 is not complete because it does not specify what happens if the sample has an adequate concentration of cells. Applicants respectfully traverse the 35 U.S.C. §112, second paragraph rejection of claim 41 and submit that

the method of claim 41 covers the situation where the solution containing the initial sample does not have an adequate concentration of cellular material. Claim 41 is not incomplete simply for not additionally stating what happens if the sample does have an adequate concentration of cells in the form of an additional (narrowing) claim limitation.

The test for definiteness under 35 U.S.C. §112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir.1986). Applicants respectfully submit that those skilled in the art would understand from reading claim 41 in its entirety that an additional sample is obtained from the patient if the solution containing the initial sample does not have an adequate concentration of cellular material, and that if the solution containing the initial sample does have an adequate concentration of cellular material, the solution containing the initial sample may be processed in a conventional way. Through this rejection, the Examiner appears to be asking Applicants to voluntarily narrow claim 41 by reciting one or more additional step relating to presently unclaimed subject matter. However, this would unnecessarily and unfairly limit Applicants' patent protection.

MPEP §2173.02 states: "if the language used by applicant satisfies the statutory requirements of 35 U.S.C. §112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. §112, second paragraph." Applicants respectfully request withdrawal of he 35 U.S.C. §112, second paragraph rejection of claim 41.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 5-7, 10-11, 14-15, 22, 24, 28-29, and 39-41 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by USP 4,129,381 (“Weid”). In order to sustain a rejection under §102, each element in the rejected claim must be found, either expressly or inherently, in the cited reference. Applicants respectfully traverse this rejection, since Weid does not disclose each and every element required by these claims. The Examiner alleges (on p. 2 of the Office Action) that Applicants characterized Weid as teaching all of the elements of the instant invention. However, Applicants are unable to find such a characterization anywhere in the prosecution history of the instant application. Applicants respectfully submit that nowhere in the prosecution history of the instant application has Weid been characterized as teaching the claimed method. In particular, Weid has not been characterized by Applicants as teaching a step of “obtaining an additional cytological sample from the patient.”

Independent claim 1 is directed to an automated method of classifying a cytological sample, wherein the method includes obtaining an additional cytological sample from the patient to be added to a solution if the solution containing an initial sample does not have an adequate concentration of cellular material. Independent claim 41 is directed to a method of determining adequacy of a cytological sample, wherein the method includes obtaining an initial cytological sample from a patient, and obtaining an additional cytological sample from the patient. In contrast, Weid teaches a method for preparing a particle suspension that includes providing a sample in solution in a vessel, optically interrogating the solution, determining whether a correct concentration of cells has been achieved, and, if the correct concentration has not been achieved, continuing to dilute and agitate the solution. Weid further teaches that, if the correct concentration has been achieved, dilution and agitation are halted. Weid does not teach or

suggest *obtaining an additional cytological sample from the patient*, and the Office Action does not address this claim element.

The Examiner alleges (at the bottom of p. 2 of the Office Action) that Weid teaches that “[i]f the sample does not contain sufficient cells, then more cells are added.” However, the Examiner does not specify where this teaching can be found, and Applicants are unable to find such a teaching anywhere in the Weid reference. Even if Weid teaches adding more cells to a sample, which Applicants do not concede, Weid still does not teach obtaining an additional cytological sample from the patient. In fact, Weid only teaches that an initial cytological sample is obtained (e.g., at col. 4, lines 36-54).

Independent claim 1 further includes attaching a manipulation designator to the vessel if the solution containing the initial sample has an adequate concentration of cellular material but requires a manipulation to render the solution containing the initial sample satisfactory for slide preparation. Weid does not teach or suggest such a manipulation designator. The Examiner states (in the paragraph spanning pages 2-3 of the Office Action) that Weid’s alleged step of adding more cells to the sample if the sample *does not contain sufficient cells* reads on the claimed “manipulation designator.” Applicants respectfully point out that claim 1 actually recites that the manipulation designator is attached if the solution containing the initial sample *has an adequate concentration of cellular material* but requires a manipulation to render the solution containing the initial sample satisfactory for slide preparation. Thus, if Weid’s sample does not contain sufficient cells, it does not meet the claimed manipulation designator criteria, and Weid’s alleged step of adding more cells does not read on the claimed step of attaching a manipulation designator.

Independent claim 41 is directed to a method of determining adequacy of a cytological sample, wherein the steps recited in claim 41 “occur in temporal conjunction.” The Examiner did not address this aspect of claim 41, and Applicants are unable to find a teaching anywhere in the Weid reference of the steps set forth in claim 41 occurring in *temporal conjunction*. Thus, Weid does not teach or suggest all of the elements of claim 41.

For at least these reasons, Applicants respectfully submit that independent claims 1 and 41, along with those rejected claims which depend therefrom, are not anticipated by Weid, and respectfully request reconsideration and withdrawal of the claim rejections under 35 U.S.C. § 102(b) based on Weid.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 5-7, 10-11, 14-15, 21-24, 28-29, and 39-41 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over US 2004/0253144 (“Isenstein”). Applicants respectfully traverse this rejection, because Isenstein does not disclose, teach, or suggest the combination of elements required by these claims.

In particular, claim 1 is directed to an automated method of classifying a cytological sample that includes attaching a positive designator to the vessel if the solution containing the initial sample has an adequate concentration of cellular material and is satisfactory for preparing a specimen slide, and attaching a manipulation designator to the vessel if the solution containing the initial sample has an adequate concentration of cellular material but requires a manipulation to render the solution containing the initial sample satisfactory for slide preparation. In contrast, Isenstein teaches a method for qualifying an automated biological screening system, wherein the

method includes a process (shown in Fig. 6) for generating a sample from which the biological qualification slides will be generated.

The Examiner indicates (on the bottom of p. 3 of the Office Action) that acceptance or rejection of a prepared slide as taught by Isenstein (e.g., in steps 124 and 126 in Fig. 6) reads on the claimed attachment of a positive or manipulation designator. However, Applicants respectfully point out that the claimed attachment of the positive designator or the manipulation designator occurs **before** a slide is prepared. For example, the positive designator indicates that the solution is **satisfactory for preparing a specimen slide**, and the manipulation designator indicates that the solution **requires a manipulation to render the solution containing the initial sample satisfactory for slide preparation**. In contrast, the method taught by Isenstein takes place after the slides have already been prepared. Thus, Isenstein does not teach or suggest the steps of attaching a positive designator or attaching a manipulation designator, as claimed.

The Examiner alleges (at the bottom of p. 3 of the Office Action) that Isenstein's acts of discarding or diluting the sample if the sample is outside of the 10-30 ASCUS+ cell range reads on the claimed act of attaching a manipulation designator. However, the claimed act of attaching a manipulation designator recites that the manipulation designator is attached "if the solution containing the initial sample **has an adequate concentration of cellular material** but requires a manipulation to render the solution containing the initial sample satisfactory for slide preparation." In contrast, Isenstein's acts of diluting or discarding the sample occur if the sample does not have an adequate concentration of ASCUS+ cells. Therefore, Applicants submit that Isenstein's acts of discarding or diluting the sample do not read on the claimed act of attaching a manipulation designator because discarding or diluting the sample as taught by Isenstein do not occur if the sample has an adequate concentration of cellular material.

The Examiner acknowledges (at the top of p. 4 of the Office Action) that Isenstein does not teach obtaining additional cytological sample from the patient. However, in the obviousness analysis, the Examiner states that “[i]t is well settled to use known techniques to improve similar methods in the same way.” However, it is respectfully submitted that to maintain a claim rejection based on this rationale requires “a finding that the prior art contained a “comparable” device (method, or product that is not the same as the base device) that has been improved in the same way as the claimed invention” (see MPEP §2143, Section C). However, no such finding has been articulated.

In the obviousness analysis (on p. 4 of the Office Action), the Examiner further states that it would have been within the skill of the art to modify Isenstein and add more cells to a sample with too low a concentration to gain the advantages of using the minimal amount of sample for analysis. First, Applicants submit that this obviousness rationale is not in commensurate scope with independent claims 1 and 41 because independent claims 1 and 41 require “obtaining an additional cytological sample from the patient.” In contrast, the obviousness rationale supplied by the Examiner states only that it would have been obvious to add more cells to a sample, not that it would have been obvious to obtain an additional sample from a patient. Second, because the method taught by Isenstein is performed on slides that have already been prepared, it would not have been obvious to one of ordinary skill to add cells to a slide that has already been prepared with a biological specimen. The Examiner has not provided any teaching of adding cells to a prepared slide, and one of ordinary skill in the art would not know how to do so without contaminating the sample and/or the prepared slide. Thus, Applicants respectfully submit that the Office Action does not set forth sufficient evidence to support a *prima facie* case of obviousness.

Claim 41 is directed to a method of determining adequacy of a cytological sample, wherein the steps in the method “occur in temporal conjunction.” The Examiner does not address this element of claim 41 and Applicants are unable to find a teaching anywhere in Isenstein of performing the steps recited in claim 41 in *temporal conjunction*. Thus, Applicants submit that Isenstein does not disclose, teach or suggest all of the elements of claim 41. For at least these reasons, Applicants submit that independent claims 1 and 41, as well as those rejected claims depending therefrom, are not obvious over Isenstein, and as such, respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of these claims. Claims 21 and 23 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Weid. Applicants respectfully traverse this rejection, because Weid does not disclose, teach, or suggest the combination of elements required by these claims.

In particular, as discussed above, Weid does not disclose, teach or suggest “obtaining an additional cytological sample from the patient,” as recited in independent claim 1, from which claims 21 and 23 depend. It is respectfully submitted that the obviousness rationale set forth in the Office Action does not cure this failed teaching. Thus, Applicants submit that claims 21 and 23 are not obvious over Weid, and as such, respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of these claims.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully submit that the pending claims are now allowable over the cited references. Applicants invite the Examiner to call the undersigned if any remaining issue(s) can be resolved through a telephonic discussion.

Respectfully submitted,
VISTA IP LAW GROUP, LLP

Dated: October 30, 2009

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